

REMARKS

These remarks are responsive to the final Office action dated September 12, 2007, and support the accompanying Request for Continued Examination as a submission under 37 C.F.R. § 1.114(c). Claims 28–30, 33–41, 83, 84, 88, and 89 are pending in the application. Claim 83 is the only independent claim. In the Office action, the Examiner rejected each of the pending claims under 35 U.S.C. § 102 or § 103 as being anticipated and/or obvious. In particular, the Examiner rejected

- Claims 28, 30, 37–41, 83, 88, and 89 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,410,255 to Pollok et al. (“Pollok”);
- Claim 29 under 35 U.S.C. § 103(a) as being unpatentable over Pollok;
- Claim 33 under 35 U.S.C. § 103(a) as being unpatentable over Pollok in view of U.S. Patent No. 5,674,698 to Zarling et al.;
- Claim 84 under 35 U.S.C. § 103(a) as being unpatentable over Pollok in view of U.S. Patent No. 6,524,790 to Kopf-Sill et al.; and
- Claims 34–36 and 83 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,586,193 to Yguerabide et al. (“Yguerabide”) in view of Pollok.

Applicants traverse the rejections, contending that none of the pending claims is anticipated or obvious. In particular, applicants believe that the Examiner, in formulating the rejections, failed to consider the amended language of claim 83, including a limitation stating that the substrate is “not capable of specifically binding to the substrate.” Furthermore, applicants have presented arguments showing that the pending claims are patentable over the cited references. Accordingly, applicants respectfully request reconsideration of the application in view of the remarks below, and prompt issuance of a Notice of Allowance covering all of the pending claims.

I. Request for Continued Examination

Applicants are submitting herewith a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. This Request complies with the requirements of 37 C.F.R. § 1.114 as follows:

- (i) Prosecution in the application is closed, since the latest Office action was a final Office action under 37 C.F.R. § 1.113.
- (ii) The Request is accompanied by a submission as set forth at 37 C.F.R. § 1.114(c), specifically, the amendments and remarks set forth herein.
- (iii) The Request is accompanied by the fee set forth at 37 C.F.R. § 1.17(e).

Accordingly, applicants respectfully request grant of their Request for Continued Examination.

II. Amended Language Not Considered

The Response to Arguments section of the final Office action states that “[a]pplicants’ arguments filed June 8, 2007 have been fully considered but are not persuasive.” Applicants disagree emphatically. The Examiner did not fully consider applicants’ arguments with respect to the amended claim language of claim 83, as set forth in the following two paragraphs.

The response to Office action filed June 8, 2007, amended the only independent claim, claim 83, as follows:

83. (Previously Amended) A kit for detecting enzyme activity in a sample, the kit comprising:
- an enzyme;
 - a luminophore bound to a substrate for the enzyme; and
 - a particulate mass label distinct from the enzyme and capable of specifically binding to ~~the substrate or~~ a product of the substrate produced by

action of the enzyme on the substrate, but not capable of specifically binding to the substrate [[both]], the particulate mass label including a bead;

wherein a luminescence property of the luminophore is sensitive to binding of the mass label to the ~~substrate or~~ product.

Previously presented/currently pending claim 83 recites a particulate mass label “capable of specifically binding to a product of the substrate produced by action of enzyme on the substrate, but not capable of specifically binding to the substrate.” In other words, the particulate mass label can bind product but not substrate.

The Response to Arguments section of the final Office action strongly suggests that the Examiner did not consider the amended language of claim 83. The Examiner stated that “[a]pplicants’ claims read on the Pollok et al. disclosure.” The Examiner then stated that “[t]o meet Applicants’ limitation at issue, the bead [of Pollok] only needs to be capable of specifically binding to the substrate, i.e., the polypeptide, but not both the product [and the substrate]” (emphasis added). Applicants disagree—the Examiner’s statement contradicts the claim language. Claim 83 recites a particulate mass label “not capable of specifically binding to the substrate.” Applicants suggest that the rejections in the final Office action were based on the language of an earlier version of claim 83, not the amended form presented on June 8, 2007. Therefore, applicants respectfully request reconsideration of the arguments that were presented in the June 8, 2007, communication from applicants and that are reproduced substantively in the following section for the Examiner’s convenience.

III. Claim Rejections – 35 U.S.C. §§ 102 and 103

The Examiner rejected all of the pending claims under 35 U.S.C. § 102(e) and/or § 103(a) as being anticipated by or obvious over Pollok alone or in combination with

another reference. Applicants traverse the rejections, contending that none of the cited references, taken alone or in combination, teaches or suggests every element of any of the pending claims.

Claim 83 reads as follows:

83. (Previously Presented) A kit for detecting enzyme activity in a sample, the kit comprising:

an enzyme;

a luminophore bound to a substrate for the enzyme; and

a particulate mass label distinct from the enzyme and capable of specifically binding to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate, the particulate mass label including a bead;

wherein a luminescence property of the luminophore is sensitive to binding of the mass label to the product.

Claim 83 was rejected in the final Office action over (A) Pollok alone and (B) Yguerabide and Pollok. However, applicants assert that claim 83 is patentable over cited references because the cited references, taken alone or in combination, do not teach or suggest every element of claim 83, for the reasons set forth below.

A. Rejections over Pollok

Claim 83 was rejected as being anticipated by Pollok. However, Pollok does not teach or suggest every element of claim 83. For example, Pollok does not teach or suggest a particulate mass label “capable of specifically binding to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate.”

Pollok relates to optical probes and assays. Figure 1 of Pollok, which is reproduced here to facilitate review, provides schematic representations of various embodiments of Pollok's probes.

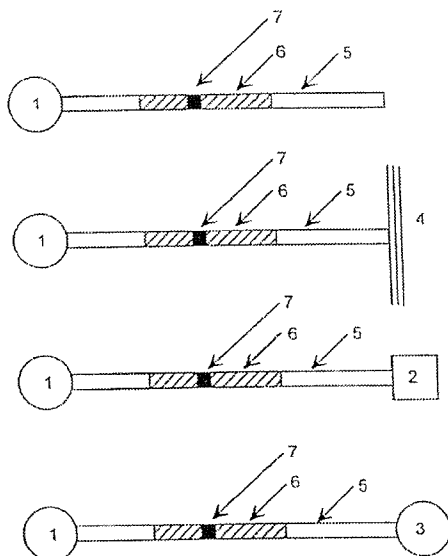


FIG. 1

Each probe is stated to include a polypeptide 5 with a post-translational modification recognition site 6, such as for phosphorylation by a kinase or dephosphorylation by a phosphatase, and a protease site 7 for protease-based cleavage of the polypeptide. The polypeptide is attached to a probe moiety 1 that provides an optical probe for optical detection of changes to the structure of the polypeptide. In some cases, the polypeptide also may be attached to a solid surface 4, such as a bead.

Pollok also discloses assays for enzymes of interest that measure enzyme activity indirectly via protease cleavage. More particularly, protease site 7 is positioned within post-translational modification recognition site 6 such that post-translational modification of site 6 by an enzyme of interest changes the efficiency with which the

polypeptide is cleaved by a protease. For example, the assays are disclosed to measure kinase activity indirectly by an effect of phosphorylation on protease cleavage of the polypeptide.

In the final Office action, the Examiner specifically cited column 25, lines 4-6, 9, and 30-36, of Pollok to reject claim 83. The cited section of Pollok involves fluorescence polarization assays that measure changes in the fluorescence anisotropy of an optical probe produced by protease cleavage. The optical probe is disclosed to have the structure presented above in Figure 1, for example, a polypeptide attached to both a bead and to a fluorescence moiety. Accordingly, Pollok discloses a bead attached to both a substrate and a product of the substrate, since the bead is bound to the substrate polypeptide before protease cleavage and remains bound to a fragment (a product) of the substrate polypeptide after protease cleavage. In contrast, claim 83 recites a particulate mass label “capable of specifically binding to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate.”

Therefore, for at least these reasons, independent claim 83 is not anticipated by Pollok. Claims 28–30, 33–41, 84, 88, and 89, which depend from claim 83, also are not anticipated by Pollok for at least the same reasons as claim 83.

B. Rejections over Yguerabide and Pollok

Claim 83 also was rejected as being unpatentable over a combination of Yguerabide and Pollok. However, neither Yguerabide nor Pollok, taken alone or in combination, teaches or suggests every element of claim 83. For example, neither reference teaches or suggests a particulate mass label “capable of specifically binding

to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate.”

Yguerabide relates to analyte assays with particulate labels. In the final Office action, the Examiner asserted that Yguerabide discloses all elements of claim 83 except a luminescent probe bound to a substrate for an enzyme, citing column 86, line 66, to column 87, line 8, of Yguerabide. The cited section of Yguerabide relates to cleavage assays in which a light scattering particle is attached to a substrate for a cleavage enzyme or ribozyme. However, Yguerabide discloses a cleavage assay analogous to that of Pollok, in which a light scattering particle is attached both to a substrate and to a product of the substrate produced by cleavage of the substrate. In contrast, claim 83 recites a particulate mass label “not capable of specifically binding to the substrate.” Accordingly, neither Yguerabide nor Pollok (see subsection A above) teaches or suggests the particulate mass label of claim 83 that binds product but not substrate.

Therefore, for at least these reasons, claim 83 should be patentable over Yguerabide and Pollok. Claims 34–36, which depend from claim 83 and also were rejected over Yguerabide and Pollok, also should be patentable over Yguerabide and Pollok for at least the same reasons as claim 83.

C. All Claims are Allowable

Claim 83 is not anticipated by or obvious over the cited references, taken alone or in combination. Claim 83 thus should be allowed. All of the other pending claims (i.e., claims 28–30, 33–41, 84, 88, and 89) depend from claim 83 and thus should be allowed for at least the same reasons as claim 83.

IV. Conclusion

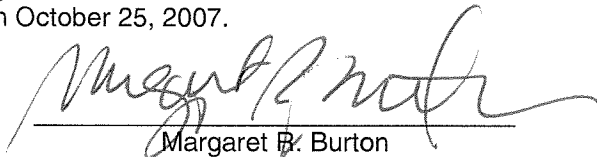
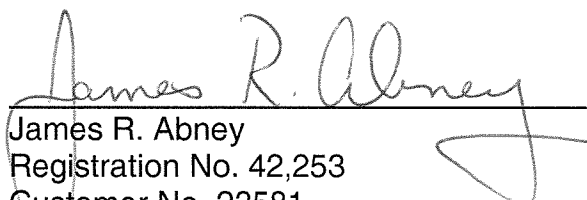
Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowance covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record, or his associate, Stan Hollenberg (Reg. No. 47,658), both at (503) 224-6655.

Respectfully submitted,

CERTIFICATE OF ELECTRONIC FILING

KOLISCH HARTWELL, P.C.

I hereby certify that this correspondence is being submitted via the EFS-Web Electronic Filing System to the U.S. Patent and Trademark Office on October 25, 2007.


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